

Maternal and Fetal Outcome in Pregnant Women with Mechanical Valve at The Royal Hospital: A Retrospective Study

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ABSTRACT

Pregnancies in women with prosthetic heart valves have historically been associated with an increased incidence of adverse outcomes for both the mother and fetus. These outcomes include miscarriage, thromboembolism, postpartum hemorrhage (PPH), and prenatal complications such as preterm birth (PTB), small for gestational age (SGA), and congenital anomalies. The design of prosthetic heart valves has continued to improve, with highly thrombogenic ball valves and large-style valves being replaced by newer bioprosthetic types. These advancements have significantly reduced the need for anticoagulant regimens during pregnancy, leading to better outcomes. Consequently, alongside improvements in obstetric and medical care, the prognosis for pregnant women with mechanical heart valves has markedly improved. However, this patient group still faces unique challenges due to the necessity of anticoagulation therapy to prevent valve thrombosis while ensuring the safety of both mother and fetus.

Introduction: Pregnancy in women with heart disease continues to be a clinical challenge due to the associated significant morbidity and pregnant women with mechanical heart valves has an increased risk of adverse outcome both maternal and fetal [1, 2]. However, the biomedical advancement in the heart valves raises the question if there is difference between the maternal and fetal outcome in the mechanical valves used: Prosthetic and Bioprosthetic heart valves. Therefore, we conducted a retrospective study to identify the maternal and fetal adverse outcome in women with mechanical heart valves and to compare the incidence of the adverse outcome between Prosthetic and Bioprosthetic heart valves pregnant women.

Materials and Methods: A retrospective study was conducted in the Obstetrics and Gynecology Department at Royal Hospital, Oman. All pregnant women with mechanical heart valves who were followed and delivered at Royal Hospital over the past 10 years (January 2010 to December 2020) were included. The collected data included maternal, pregnancy, and fetal details based on the literature review. Data was collected from the Alshifa Electronic Medical Record System, and statistical analysis was performed using SPSS software. Fisher Exact test was used for measuring the statistically significant relationship between Prosthetic, Bioprosthetic and the outcome.

Result: A total of 301 patients were included. 61 patients (20.3%) were Primi-gravida whereas (79.7 %) were women with multiple pregnancy. Bioprosthetic valve found in 199 patient (66.1%) of the included patients. (82.4%) 248 patient were with single valve replacement. The most common of replacement valve replacement Rheumatic heart disease by (59.5%). Since majority of the patient were with Bioprosthetic valve, (65.8%) were not on anticoagulation therapy. Regarding maternal outcome: Mortality rate was (2%), whereas other complication including valve thrombosis, PIH were (3%), Miscarriage was found in 21.3% of the cases and was seen more with patient who were on warfarin. The rate of cesarean section was (23%) comparing to spontaneous vaginal delivery (77%). Termination was indicated on 5 patient (1.7%) with variable reasons for terminations including maternal and fetal indications. For the Fetal outcome: 193 (64.1%) term, 15 (5%) preterm, out of which 43 (14.3%) required NICU admission. Perinatal mortality was (1.3%). 53 (17.6%) were Low Birth weight newborn. And 3 cases (1%) with fetal anomalies.

Conclusions: Women with heart valve experienced highly risk of adverse outcome then expected in general obstetric population. Women with Bioprosthetic have less adverse outcome. Balancing the risks of thrombosis and bleeding complications during pregnancy is critical for optimal maternal and fetal outcomes. Multidisciplinary pre-pregnancy counselling is important.

Keywords: Heart Valve, Anticoagulation, Maternal Outcome, Fetal Outcome

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Introduction

Pregnancy is associated with several physiological changes including: cardiovascular changes and hyper coagulation state. Physiological cardiovascular changes including an increase in cardiac output, fluid retention, blood volume expansion which impact underlying cardiac disease. The changes begin in early pregnancy and peak in second trimester Due to hypercoagulable state the risk of thromboembolic complications is higher during pregnancy. Pregnancy after mechanical heart valve replacement carry a risk for mother and fetus. Risks include maternal heart failure, arrhythmia, infectious endocarditis, and maternal death with advancing gestational age. The risk of complications during pregnancy in a patient with prosthetic heart valve (PHV) depends on the type, position, and function of the valve as well as cardiac function, patient's symptoms, and functional capacity.

Therapeutic anticoagulation is recommended for all pregnant women with mechanical valve to prevent valve thrombosis and thromboembolic events. Warfarin offer the best protection against thromboembolic complications in women with mechanical heart valves, but it freely crosses the placenta and it is associated embryopathy with exposure during the first trimester. The teratogenic effects is more with warfarin doses more than 5 mg/day. Unfractionated heparin (UFH) and low-molecular-weight heparin (LMWH) do not cross the placenta are associated with higher rates of maternal valve thrombosis.

Pregnancy in women with heart disease continues to be a clinical challenge due to the associated significant morbidity and pregnant women with mechanical heart valves has an increased risk of adverse outcome both maternal and fetal [1, 2]. However, the biomedical advancement in the heart valves raises the question if there is difference between the maternal and fetal outcome in the mechanical valves used: Prosthetic and Bioprosthetic heart valves. Therefore, we conducted a retrospective study to identify the maternal and fetal adverse in women with mechanical heart valves and to compare the incidence of the adverse outcome between Prosthetic and Bioprosthetic heart valves.

Methods

A retrospective cross-sectional study was conducted after obtaining ethical approval from the Center of studies and research- Ministry of health and Royal Hospital (SRC#64/2022). It included all pregnant women with mechanical heart valve who were follow up and delivered in Royal Hospital from January 2010 to December 2020. Pregnant women with medical comorbidity, Pregnancy associated co-morbidities and women who delivered outside Royal hospital were excluded from the study. The information was obtained from the outpatient visit, delivery suite registry and electronic patient records.

Data collection sheet was designed to obtain the following information:

1. Maternal demographics (age, gravidity, parity, past medical and obstetric history)
2. Current pregnancy associated comorbid (GDM, PIH, asthma, sickle cell disease, Chronic hypertension, Thalssesmia, obesity)
3. Mechanical valve history (type of valve, location and number of valve replaced, reason of replacement)
4. Use of anticoagulation (type of anticoagulant)

5. Maternal outcome (Delivery details : mode of delivery, miscarriage, new arrhythmia, post-partum hemorrhage, valve thrombosis, myocardial infraction, termination of pregnancy, mortality)
6. Fetal outcome (Low birth weight, small for gestational age, Neonatal Intensive Care Unit (NICU) admission, cardiac problem, term, preterm, perinatal mortality, fetal anomalies due to warfarin use) See Appendix 1. The data was collected from Alshifa Electronic Medical Record System and SPSS statistical program was used for data analysis. Fisher Exact test was used for measuring the statistically. significant relationship

Results

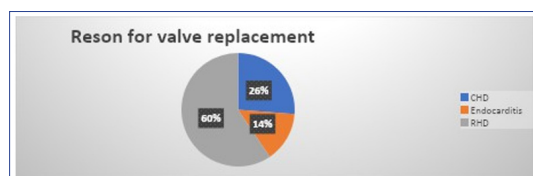
Based on Inclusion and Exclusion criteria of study duration of 10 years, 301 pregnancies were included in the study. The excluded cases were cases with other medical comorbidity, fifty eight patient with gestational diabetic, 14 patient with pregnancy induced hypertension, 7 patient with asthma, 3 patient with sickle cell disease , 4 patient with chronic hypertension disease, Forty five patient were following in antenatal clinic in royal hospital but did not delivered in Royal hospital so were excluded. Among included pregnancies, 61 patients (20.3%) were primigravida, while 240 patients (79.7%) had multiple pregnancies.

The median maternal age was 31 years (range: 18- 47 years), while the median gravidity and parity were three (range: 1-2). Table 1.

Table 1: Maternal Demographics

Age			BMI	Parity	No. of fetus
N	Valid	301	301	284	301
	Missing	0	0	17	0
Mean		31.23	27.32	1.79	1.03
Median		31.00	25.00	2.00	1.00
Std. Deviation		5.26	4.79	1.51	20.
Minimum		20.00	20.00	00.	1.00
Maximum		43.00	43.00	9.00	3.00
Percentiles	25	27.50	24.00	1.00	1.00
	50	31.00	25.00	2.00	1.00
	75	35.00	31.00	2.00	1.00

Bioprosthetic valves were present in 199 patients (66.1%), and 248 patients (82.4%) had a single valve replacement. The causes of valve replacement varied, with rheumatic heart disease being the most common, accounting for 59.5% of the cases, followed by congenital heart disease and infective endocarditis. (26.2%, 14.3% respectively) (Chart 1). cases (82.4 %) of cases were with single valve replacement where multiple valve 248. (% replacement was seen in 53 patients (17.6 Valve location: Mitral 60.8%, Aortic 22.9%, both valve replacement 16.3% (183 patient, 69. (patient and 49 patient respectively Since most patients had bioprosthetic valves, 65.8% were not on anticoagulation therapy. 34.2% were on anticoagulation among then 26.2% were on anticoagulation before the pregnancy and 8.2% of patients started on anticoagulation after the pregnancy 29% were on heparin and 75% were on warfarin.

**Chart 1:** Reason for valve replacement**Maternal Outcomes**

Total of 9 different adverse obstetric events were recorded in our study. The mortality rate was 2%, with other complications, including valve thrombosis and pregnancy-induced hypertension (PIH), occurring in 3% of the cases. Miscarriage was observed in 21.3% of the patients and was more common in those on warfarin. Postpartum hemorrhage (PPH) (6.3%), new arrhythmia (7.6%), Thromboembolism (1.7%), valve thrombosis (3%) (Table 2).

Adverse obstetric outcome		
	Number	(%) Percent
Mortality	6	2
Postpartum haemorrhage	19	6.3
Valve thrombosis	9	3
Miscarriage	64	21.3
Thromboembolism	5	1.7
Termination of pregnancy	5	1.7
New arrhythmia	23	7.6
Stroke	2	0.7
Myocardial infraction	4	1.3

The section cesarean rate was 23%, compared to 77% for spontaneous vaginal delivery. Pregnancy termination was indicated in 5 patients (1.7%) for various maternal and fetal reasons. (Table 3).

Delivery mode		
	Number	(%) Percent
SVD	138	45.8
Cesarean section	71	23.6

Fetal the 193 term 15 43 Outcomes: Of pregnancies, (64.1%) resulted in deliveries, and (5%) were preterm, with (14.3%) requiring NICU admission. Perinatal mortality was 1.3%. There were 53 (17.6%) low birth weight newborns and 3 cases (1%) of fetal anomalies. (Table 4).

Fetal outcome		
	Number	(%) Percent
Low birth weight	53	24
Small for gestational age <10th centile	43	19.5
NICU admission	43	19.5
Cardiac problem	8	3.7

Prenatal mortality	4	1.9
Neonatal death	2	0.7
Fetal anomalies	3	1.5
Term	193	88.5
Preterm	15	7

Comparison Parameters Between Prosthetic Valve Group and Bioprosthetic Valve Group:

- **Maternal Mortality:** The overall maternal mortality rate was low, with no statistically significant difference between the prosthetic valve group and the bioprosthetic valve group (2.1% vs. 2.2%, $p=0.970$).
- **Myocardial Infarction:** The incidence of myocardial infarction was slightly higher in women with prosthetic valves compared to those with bioprosthetic valves (2.1% vs. 1.1%), although this difference was not statistically significant ($p=0.498$).
- **Pregnancy-Induced Hypertension:** Women with prosthetic valves had a higher, though not statistically significant, incidence of pregnancy-induced hypertension compared to those with bioprosthetic valves (5.3% vs. 2.2%, $p=0.166$).
- **Postpartum Hemorrhage:** Postpartum hemorrhage was more common in the prosthetic valve group compared to the bioprosthetic valve group (9.6% vs. 5.5%), but this difference did not reach statistical significance ($p=0.209$).
- **Stroke:** The incidence of stroke was low in both groups, with no significant difference between the prosthetic and bioprosthetic valve groups (1.1% vs. 0.5%, $p=0.633$).
- **Valve Thrombosis:** The rates of valve thrombosis were similar between the prosthetic and bioprosthetic valve groups (3.2% vs. 3.3%, $p=0.963$).
- **Miscarriage:** A significantly higher rate of miscarriage was observed in the prosthetic valve group compared to the bioprosthetic valve group (37.2% vs. 15.9%, $p<0.001$).
- **Thromboembolism:** There was no significant difference in the incidence of thromboembolism between the two groups (0.0% in the prosthetic valve group vs. 2.7% in the bioprosthetic valve group, $p=0.105$).
- **Cesarean Section:** The rate of cesarean section was similar between the prosthetic and bioprosthetic valve groups (23.4% vs. 26.9%, $p=0.526$).
- **Spontaneous Vaginal Delivery (SVD):** The bioprosthetic valve group had a significantly higher rate of spontaneous vaginal delivery compared to the prosthetic valve group (55.5% vs. 39.4%, $p=0.011$).
- **Termination:** The rate of pregnancy termination was low and did not differ significantly between the groups (1.1% for the prosthetic valve group vs. 2.2% for the bioprosthetic valve group, $p=0.507$).
- **New Arrhythmia:** New arrhythmias were significantly more common in the bioprosthetic valve group compared to the prosthetic valve group (11.0% vs. 3.2%, $p=0.027$).
- **Low Birth Weight:** There was no significant difference in the incidence of low birth weight between the prosthetic and bioprosthetic valve groups (22.4% vs. 24.8%, $p=0.695$).

Discussion

Our study aimed to identify the maternal and fetal outcomes in women with mechanical valves and compare their incidence

between prosthetic versus bioprosthetic heart valves during pregnancy in the Royal Hospital Obstetrics and Gynecology department. The overall maternal mortality rate in our cohort was low (2%), consistent with the findings of Siu et al. who reported low maternal mortality in women with heart disease during pregnancy. However, unlike Siu et al., who noted a higher incidence of cardiac complications, our study did not find a statistically significant difference in mortality between the prosthetic and bioprosthetic valve groups. These findings came consistent with Vause et al who also reported comparable maternal outcomes between women with mechanical and bioprosthetic valves [3].

However, the incidence of pregnancy-induced hypertension (PIH) was higher in women with prosthetic valves (5.3%) compared to those with bioprosthetic valves (2.2%), although this difference was not statistically significant. Similar finding was also observed by Bonnaud et al. and noted higher pregnancy-related complications, including PIH, in women with mechanical valves [4]. The increased rate of PIH in women with prosthetic valves may be attributed to the hemodynamic burden imposed by the valve type. Miscarriage rates were notably higher in the prosthetic valve group (37.2%) compared to the bioprosthetic valve group (15.9%, $p < 0.001$) which is consistent with Van Hagen et al.

In his paper, Van Hagen et al suggested that there is an increased risk of miscarriage in women with mechanical heart valves can be attributed to the need for anticoagulation therapy during pregnancy [5]. Yinon et al reported increased risk of miscarriage with Warfarin use [6]. Warfarin is known to be a teratogenic agent with associated adverse pregnancy outcomes, including miscarriage [7]. On the other hand, McLintock et al. reported that enoxaparin was effective in managing pregnant women with mechanical prosthetic heart valves, contributing to a relatively low incidence of severe maternal complications [7]. James et al also reported low maternal morbidity with low molecular heparin [8]. Regarding fetal outcomes, the rate of preterm delivery in our study is 5%. It is lower than the reported incidence by Elkayam and Bitar et al. In their paper, they found higher rates of preterm birth in women with mechanical valves [9].

The lower preterm delivery rate in our study may reflect better management and monitoring of pregnant women with heart valve prostheses in our setting and in the healthcare system in Oman. As these patient are following in Obs-cardiology clinic, which is a combined clinic between obstetrician and cardiologist. However, the rate of low birth weight (LBW) newborns in our cohort (22.4% in prosthetic valve group vs. 24.8% in bioprosthetic valve group) was comparable to the findings in the study by Bonnaud et al., where LBW was a common complication among infants born to mothers with heart valve prostheses [4]. This suggests that fetal growth restriction remains a significant concern in these pregnancies, possibly due to maternal hemodynamic compromise and medication effects.

Nevertheless, our study found that women with prosthetic valves were more likely to undergo cesarean section (C-section) and had a lower rate of spontaneous vaginal delivery (SVD) compared to those with bioprosthetic valves. These results are consistent with Van Hagen et al. who reported higher C-section rates in women

with mechanical valves due to the perceived higher risk of complications during vaginal delivery [5]. However, Al-Malki et al concluded that both vaginal delivery and C-section can be carried safely on individual bases [10]. On the other hand, the incidence of new arrhythmias was significantly higher in the bioprosthetic valve group (11.0%) compared to the prosthetic valve group (3.2%). This finding is not usually reported, and the literature review did not show any consistent results. This difference might be related to the differing hemodynamic profiles of the two valve types or pre-existing conditions in patients opting for bioprosthetic valves. Further research is needed to investigate this observation.

Conclusions

Women with mechanical heart valves are at a significantly higher risk of adverse outcomes compared to the general obstetric population. While maternal and fetal outcomes were generally favorable, the significantly higher miscarriage rates in the prosthetic valve group and the increased risk of new arrhythmias in the bioprosthetic group highlights the need for close monitoring and timely management for these high-risk pregnancies.

Limitations

Our study has some limitations. As it was conducted retrospectively, we faced missing data in some aspects, Moreover, no control group. Variable Anticoagulation Protocol were carried out by cardiologist and maternal medicine obstetrician. Single Center. For future studies, we recommend focusing on specific adverse obstetric and fetal outcome, correlating the outcome to maternal medical risk. And sub-divide the patient in to group according to type of heart disease (Mitral-Aortic/Regurgitations-stenosis/ mechanical; or homograft valves). A case-control study with a larger sample size including multiple centers is recommended.

Conflict of Interest: The Authors Declare to Conflict of Interest.

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